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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/812,849	ZANKEL ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-19,21,22 and 58-62* is/are pending in the application.

4a) Of the above claim(s) *22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-19,21 and 58-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *17-19,21,22 and 58-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/16/04, 6/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's remarks and amendments filed 21 June 2006 have been entered. Claims 1 – 16, 20, and 23 – 57 are canceled; claims 58 – 62 are new. Claims 17 – 19, 21 – 22, and 58 – 62 are pending.

Election/Restrictions

2. Applicant's election with traverse of Group II in the reply filed on 21 June 2006 is acknowledged. The traversal is on the ground(s) that claim 18 was improperly included in Group I. Applicant's arguments are persuasive; claim 18 will be examiner in the instant office action.

3. As a courtesy to applicant, the following requirements for elections of species are withdrawn:

A. The requirement to elect a specific megalin-binding moiety.

B. The requirement to elect a single therapeutic agent.

C. The requirement to elect a single neurodegenerative disease selected from the group consisting of Huntington's Disease, Alzheimer's Disease, Parkinson's Disease, Multiple Sclerosis, Amyotrophic Lateral Sclerosis, spinal muscular atrophy, and cerebellar degeneration is withdrawn. However, the requirement is maintained with respect to the other diseases recited in claim 21, which are not reasonably neurodegenerative diseases. Search for methods of treating any of the above-listed neurodegenerative diseases would not be expected to be informative on the novelty or non-obviousness of treating ischemia-related disease and stroke, perivenous encephalitis, schizophrenia, epilepsy, or a CNS cancer.

4. Claim 22 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 21 June 2006. Applicant elected Huntington's Disease as the specific disorder, but did not specifically point out which claims read on the elected invention. Claim 22 is limited to cancer, not Huntington's Disease.

5. Claims 17 – 19, 21, and 58 – 62 are under examination.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17 – 19, 21, and 58 – 62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of delivering agents to the CNS by administering said agent conjugated to human Receptor Associated Protein (RAP) with the sequence of SEQ ID NO:1, does not reasonably provide enablement for all megalin binding moieties lacking defined structure as recited in claims 17 – 19. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (FED. Cir. 1988).

The claims encompass methods of administering conjugates between any megalin binding moiety, of any structure, and agents to be transported across the blood brain barrier (BBB). The examiner concedes that agents to be transported across the BBB are well-known in the art. However, the term "megalin binding moiety" has no structure and thus it would take undue experimentation for the skilled artisan to make and use the full scope of agents to be administered in the claimed method.

The specification discloses that one of the preferred megalin binding agents is the polypeptide known as RAP, for receptor associated protein. The human RAP sequence is disclosed to be that of SEQ ID NO:1. However, the scope of "megalin binding moiety", recited in claims 17 – 19, is considerably broader than this specific sequence. The scope of the claim includes any and all molecules that bind to megalin, whether they are proteins, antibodies, small organic molecules, or non-organic molecules.

With respect to RAP, the work of Medved et al. (1999. J Biol Chem 274:717-727, reference C37 on IDS filed 16 June 2004) is particularly informative. Working with human RAP, Medved et al. found that the molecule is made up of four domains, from residues 1 – 92, 93 – 163, 164 – 216, and 217 – 323 (see p. 727, final paragraph). Medved et al. also teach that sequence similarity is not an appropriate method to deduce function of this protein (see p. 726, first paragraph of Discussion), as it leads to an erroneous prediction of the number of domains. Medved et al. teach that domains 1, 2, and 4 all are involved in binding of RAP to the receptor LRP, and since the instant invention is based upon RAP's role as a LRP ligand (specification, p. 4, second paragraph) clearly these regions are necessary for the invention to work. However, the human sequence is not identical to any of the other species in these regions, as evidenced by Figure 14, and there is no requirement in the claims that any particular region be present in the RAP molecule.

The claims are broad, in that they are include to any RAP as well as any megalin binding moiety of any structure. There is no requirement that the moiety be internalized, or be able to cross the BBB. The nature of the invention, construction of fusion proteins, is complex. The art, as it is drawn to relationships between protein sequence and function is unpredictable. The only working examples of RAP-conjugated enzymes involve the human sequence. Therefore, it would require undue experimentation on the part of a skilled artisan to make and use the starting materials required for the instant method commensurate in scope with the claims.

7. Claims 17 – 19, 21, and 58 – 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims encompass methods of administering structures defined only by their ability to bind to megalin. No specific structural elements must be present in the megalin binding moiety. The specification describes human RAP with SEQ ID NO:1, and contemplates certain variants but does not disclose actual variant proteins. The full genus of the megalin binding moieties encompassed by the claims cannot be immediately visualized by the skilled artisan.

Applicant is directed to the flow chart on p. 9 of the Revised Written Description Interim Guidelines Training Materials, available on the internet at

<http://www.uspto.gov/web/offices/pac/writtendesc.pdf>, which is analogous to the instant situation. Claims 17 – 19 are genus claims, but neither the art nor the specification discloses a representative number of species falling within the genus. There is not even identification of any particular portion of the structure at either the nucleic acid or amino acid level that must be conserved. The genus of megalin-binding moieties to be conjugated to the appropriate agent is not limited to any particular type of molecule, such as a protein. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 and 58 – 62 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: administering an agent to an animal. The preamble of claim 18 indicates that the goal is to increase the transcytosis of an agent across the BBB. However, the only step enumerated in the method is conjugating said agent to a moiety. Simply conjugating the agent will not increase its transport across the BBB; until the agent is actually administered it will not be transported across the BBB. Claims 58 – 62 each depend from claim 18 and therefore are rejected for the same reasons.

9. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 depends from claim 20, however claim 20 is canceled. The skilled artisan could not determine the metes and bounds of the patent protection sought by claim 21.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

As set forth in the rejection under 35 USC 112, second paragraph above, claim 21 depends from canceled claim 20. However, for the purposes of applying prior art, the examiner has presumed that this is an inadvertent error and that the claim actually should depend from one of the independent claims that precedes it.

Claims 17 – 19, 21, and 58 – 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Beliveau (US Patent Application Publication 2003/0129186, published 10 July 2003, filed 25 July 2002, claiming benefit of a provisional application filed 25 July 2001).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Beliveau teaches conjugates comprising "a peptide ligand of the LRP1 or LRP1B receptor" (see p. 3 paragraph [0026]), and teaches that RAP is such a ligand (see p. 13, Table 3), and also teaches that RAP is a megalin-binding moiety (see Figure 17C). Beliveau also teaches administering the conjugates to animals (see for example p. 3 paragraph [0028]). Thus Beliveau anticipates every limitation of claim 17 and 19. Claim 18 is rejected as Beliveau teaches how to conjugate the agents, note that claim 18 requires no active steps other than conjugating.

Claims 21, 58, and 59 are rejected as Beliveau teaches treatment of Huntington's disease with any of the compounds disclosed of his invention (see p. 12, paragraph [0129]), and particularly mentions that the compositions of the invention should be formulated for administration to humans (see for example p. 19, paragraphs [0197] – [0198]).

11. Claims 17 – 19, 21, and 58 – 59 are rejected under 35 U.S.C. 102(a) as being anticipated by Beliveau (WO 03/009815, published 6 February 2003).

The Beliveau '815 publication is identical to the '186 publication above; it appears to differ only in the numbering of the pages. Both publications resulted from applications filed on the same day and claim benefit of the same U.S. Provisional Application. The reasons why the disclosure anticipates the invention of claims 17 – 19, 21, and 58 – 59 are set forth in the previous rejection.

12. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Czekay et al. (1997. Molecular Biology of the Cell 8:517-532, cited on IDS filed 16 June 2004).

Claim 18 does not require administration of the conjugate to any subject; the only active step of the method is "conjugating". Czekay teaches conjugating GST to receptor associated protein, or RAP. The conjugate was a recombinant fusion protein; see p. 518 second column. As RAP is a megalin-binding moiety (see specification, p. 5, final paragraph for example) and the reference by Czekay teaches conjugating GST, which is an agent, to RAP, it fairly anticipates every step of claim 18.

13. Claims 17 – 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Zlokovic (1996. Proc Natal Acad Sci USA 93:4229-4234), as evidenced by Schenck (U.S. Patent 6,743,427).

Zlokovic teaches complexes between apoJ and beta-amyloid (sAβ1-40), as well as administration of these complexes to animals. Zlokovic teaches how to make the complexes on p. 4230, first column. Zlokovic teaches that apoJ is a ligand for megalin, which is also referred to in the text as gp330 (see for example abstract), and that the transport of the apoJ-sAβ1-40 complex across the BBB is very high (see p. 4232, second column). Zlokovic is silent as to whether or not Aβ is therapeutic. However, Schenk provides evidence that the 40-amino acid version of Aβ is a therapy for Alzheimer's disease. See for example column 27 lines 24 – 59, which discuss administration of Aβ to patients as a way to elicit an immune response. Note particularly lines 26 – 31, which discuss the importance of having the agent cross the BBB. Schenk also provides an example of therapy of a mouse model of Alzheimer's disease by administration of Aβ (see example 1 beginning at column 33). Thus Schenk provides evidence that the Aβ used in the complexes of Zlokovic is a therapeutic agent. Therefore the teachings of

Zlokovic anticipate the methods of claims 17 and 19. Claim 18 does not require administration of the conjugate to any subject; the only active step of the method is "conjugating". As Zlokovic teaches the complexes, which are reasonably conjugates the reference anticipates the invention of claim 18.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17 – 19, 21, and 58 – 62 are rejected under 35 U.S.C. 103(a) as being obvious over Beliveau (U.S. Patent Application 2003/0129186) in view of Perez-Navarro (2000. Journal of Neurochemistry 75:2190-2199), or in the alternative over Beliveau (WO 03/009815), in view of Perez-Navarro.

The applied reference Beliveau (U.S. Patent Application 2003/0129186) has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned

by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2). Note that these conditions apply only to the reference by Beliveau (US Patent Application Publication 2003/0129186), and not to WO 03/009815, which qualifies as prior art under 102(a).

The reasons why both Beliveau (U.S. Patent Application 2003/0129186) and Beliveau (WO 03/009815) both anticipate claims 17 – 19, 21, and 58 – 59 are set forth in the rejections under 35 USC 102 above. Briefly, both references teach administration of conjugates between RAP and therapeutic agents for treatment of disease, including Huntington's disease. Beliveau ('186 publication) teaches that growth factors can be used in the conjugates (see p. 3 paragraph [0026]). However Beliveau does not teach using BDNF in the conjugate.

Perez-Navarro teaches that BDNF is neuroprotective when administered to rats in an art-accepted model of Huntington's disease. Thus the reference is on point to claims 21 and 59, which encompass Huntington's disease, and claims 60 – 62, which encompass BDNF. Specifically the Perez-Navarro reference teaches that quiniolate, when injected into the striatum, replcates many of the neurochemical, histological, and behavioral features of the disease (see first paragraph of the text), and that grafting cells which secrete BDNF into the striatum protects against toxicity of several types of neurons studied (see pp. 2195 – 2197). Furthermore, the authors contemplate that neurotrophins, including BDNF, should be used for treatment of neurological disorders (see p. 2198, final paragraph).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Beliveau (either the '186 publication or '815 publication) to use BDNF as the active agent, as taught by Perez-Navarro. The motivation to do so would be to treat Huntington's disease. Beliveau teaches that the conjugates can be used to transport active agents across the BBB, and that Huntington's disease is one of the conditions that can be ameliorated by administering the conjugates. Perez-Navarro teaches that Huntington's disease can be treated by administration of BDNF to the brain, thereby guiding the artisan to select this particular neurotrophic factor for the treatment of this disease.

15. Claims 17 – 19, 21, and 58 – 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zlokovic (1996. Proc Natal Acad Sci USA 93:4229-4234) in view of Schenk (U.S. Patent 6,743,427, issued 1 June 2004, filed 28 November 2000, claiming benefit of filed applications filed between 2 December 1997 and 26 May 2000).

The reasons why Zlokovic anticipates the method of claims 17 – 19 and 21 are set forth in the rejection under 35 USC 102 above. However, while Zlokovic teaches administration of the complexes to rats, Zlokovic does not teach administration of the complexes to humans.

Schenk teaches administration of beta-amyloid peptide to humans for treatment of Alzheimer's disease. Schenk teaches that the Aβ1-40 form may be used (see column 10 lines 1 – 43, for example), and teaches that the artisan should ensure that the peptide crosses the blood-brain barrier (see column 27 lines 24 – 31). Furthermore Schenk teaches that the agents are to be administered to humans suffering from Alzheimer's disease (see for example column 25 first paragraph and column 8 lines 50 – 53), and thus is on point to claims 58 and 59.

It would have been obvious to one of ordinary skill in the art to administer the complexes of Zlokovic to humans suffering from Alzheimer's disease. The motivation to do so would be to treat Alzheimer's disease, and comes directly from the prior art references themselves. Zlokovic teaches that the conjugates comprising Aβ rapidly and efficiently crosses the BBB, and Schenk teaches that Aβ should be administered to human patients for treatment of Alzheimer's, and that one should ensure the compositions cross the BBB.

16. Claims 17 – 19, 21, and 58 – 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zlokovic in view of Schenk as applied to claims 17 – 19, 21, and 58 – 59 above, and further in view of Perez-Navarro (2000. Journal of Neurochemistry 75:2190-2199).

The reasons why claims 17 – 19, 21, and 58 – 59 are obvious over Zlokovic in view of Schenk are set forth in the previous rejection. However, neither of those references teaches conjugates comprising BDNF.

Perez-Navarro teaches that BDNF is neuroprotective when administered to rats in an art-accepted model of Huntington's disease. Thus the reference is on point to claims 21 and 59, which encompass Huntington's disease, and claims 60 – 62, which encompass BDNF. Specifically the Perez-Navarro reference teaches that quiniolate, when injected into the striatum, replcates many of the neurochemical, histological, and behavioral features of the disease (see first paragraph of the text), and that grafting cells which secrete BDNF into the

striatum protects against toxicity of several types of neurons studied (see pp. 2195 – 2197). Furthermore, the authors contemplate that neurotrophins, including BDNF, should be used for treatment of neurological disorders (see p. 2198, final paragraph).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Zlokovic to use BDNF as the active agent, as taught by Perez-Navarro. The motivation to do so would be to treat Huntington's disease. Zlokovic teaches that conjugates comprising ApoJ rapidly cross the BBB, and Perez-Navarro teaches that Huntington's disease can be treated by administration of BDNF to the brain, thereby guiding the artisan to select this particular neurotrophic factor for the treatment of this disease.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17 – 19, 21, and 58 – 62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3 – 6 and 14 of copending Application No. 11/202566. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic with respect to the structure of the megalin-binding moiety, while the claims in the '566 application are specific in that they require at least 80% sequence identity to RAP. Thus the claims in the '566 application would anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Inventorship

18. Claims 17 – 19, 21, and 58 – 62 are directed to an invention not patentably distinct from claims 3 – 6 and 14 of commonly assigned 11/202566 as set forth in the double-patenting rejection above. The inventive entities are not identical between the '566 application and the instant application, and there is not evidence of record that the two applications are currently commonly assigned.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 11/202566, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DK

Daniel E. Kolker, Ph.D.
August 24, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER